Genes and TRIPS: No Man's Land Revisited?[1]

"…justice is the restraint of conflicting greeds."

Clodia, in *The Ides of March* by Thorton Wilder.

Abstract

New technology is not always and not only a vehicle of wealth creation; it can also be a vehicle of wealth appropriation, given the proper legal regime. Through a complex regulatory system, stemming from the intersection between domestic law and international intellectual property rights agreements (TRIPs), technology has become a means through which developed economies can appropriate the natural resources of biodiverse, yet technologically poor, countries. Intellectual property law regulates technology with deeply entrenched biases that disregard "low tech" means of innovation and wealth creation –such as the development of new strands of food varieties or identification of medicines through traditional selective breeding or traditional medicine– while simultaneously overvalues "high tech" applications which do not necessarily create or innovate.

Thus, as applied to biodiversity and biotechnology, specifically the field of genetics, the international intellectual property rights regime in place hinders innovation –or at the very least, hinders the innovators–, contrary to the commonplace understandings that

[1] I presented the original version of this paper at Bo Burt's course *Genetics, Ethics, and the Law* at Yale Law School in the spring of 2003. I've revised and updated the original paper for this edition of SELA, but the core idea –that the TRIPS regime parallels the *terra nullius* doctrine in two significant ways: how it works and what it results in– comes from that original paper. I want to thank Ivan Saldaña Oyarzábal, for drawing I attention to the phenomenon labeled "biopiracy" in the first place, and specifically to the importance of the TRIPS agreement. I would also like to thank my research assistant, Estefanía Vela Barba, for helping me update and revise the paper and Catalina Perez Correa, my wife, for reviewing the updated version and helping me revise it for SELA 2011.

justify intellectual property rights. The resulting intellectual property rights regime parallels the conceptual underpinning of the colonial doctrines through which Europeans supported their claims over America: just as native political organization were as invisible to the conquistadors in the 16th century, "low tech" innovation is invisible to intellectual property rights regime today. Then, the lack of proper polities by dominated peoples justified conquest; today their lack of *proper* technology justifies appropriation of knowledge and resources.

Modern day markets no longer need to *conquer* foreign lands to appropriate their wealth, they need only *patent* the natural resources –notably, the biodiversity– of those foreign lands. In this sense, the *function* the current international intellectual property right regimes, as applied to biodiversity and biotechnology, replicates the colonial doctrine of *terra nullius*: the appropriation of the natural resources of weak nations by dominant economies. It also *works* in a similar fashion: it renders traditional technology and knowledge invisible.

Introduction

It is commonplace, almost cliché, to speak of technology innovation as a means of wealth creation. Innovators and inventors are presumed to contribute disproportionately to the general wellbeing by creating wealth directly or else opening new paths to wealth creation. To enhance innovation and wealth creation, innovators are rewarded with an artificial benefit (monopoly) from their inventions and technological developments. The law has long subscribed this thesis and, in accordance, has established intellectual property rights to stimulate wealth creation through innovation.

Over a decade ago, when the human genome was first fully described, we were told that we were lucky to live through the deciphering of the Book of Life, the drafting of the "most wondrous map ever produced by humankind"[2]; that we were to gaze in awe at the accomplishments of the human mind. Some think that this quasi-miraculous achievement

[2] Bill Clinton on the completion of the first survey of the entire Human Genome Project on June 26, 2000 as quoted in LORI B. ANDREWS ET. AL., GENETICS: ETHICS, LAW AND POLICY (2002) at 29.

will transform human development by empowering us to tailor and design ourselves and our environment to our advantage. Others see this as just another technological and scientific advance, like the hundreds we have seen over the last hundred years, and are likely to see more frequently in the future. Still others warn that this arrogant tinkering with nature, this "playing God", will lead to no good.

Regardless of which –if any– of the three narratives is right, the hype about genetics has had a disparate impact on the different groups of people involved in these developments. I want to illustrate this disparate impact at the intersection of intellectual property rights and the development of biotechnology. I also want to argue that this is not a new phenomenon: legal doctrines often carefully exclude certain aspects of reality from its horizon, enabling these inequities. As I said, this exclusion enabled law to justify colonialism. Today intellectual property rights regime as applicable to genetics, enables the appropriation of the natural resources and knowledge of peripheral cultures by the dominant economies. In a very real and tangible way, it enables colonialism.

Advances in genetics benefit differentially because the different actors involved in the development of biotechnology are differently regarded (or disregarded) by the hype about genetics and, accordingly, by the law. While researchers and biotech industries are given the spotlight and covered in prices (in the form of property rights which effectively monopolize genes), other actors –of whom I'll speak more in the next section- disappear into the background and are rendered invisible by the dazzle that the geno-hype pours over its darlings. Geno-hype, when translated into the law that regulates how the commercial benefits of genetic knowledge are distributed, is selective. And, it selectively favors the wealthy.

The purpose of this paper is two-fold. I will attempt to establish a schematic picture of the legal framework regarding patents on genetic materials by trying to describe how the legal instruments at the international and national levels tie together. In doing so I hope to illustrate how the inhabitants of the land from which knowledge and genetic resources are obtained come to be invisible. I also want to illustrate how legal distinctions, which are arbitrary and not analytically sound, are at the source of this invisibility.

Two stories, with divergent underlying narratives

Allow me to evoke some images. Picture a brilliant, young scientist in a small New Haven biotech lab that toils over test-tubes, computer screens, and flashing lights. After years of hard, meticulous research she discovers that a certain gene in wheat is responsible for the production of Vitamin X, which in turn is responsible for producing white blood cells. If one was to enhance that gene and plant wheat –also extra rich in Vitamin X– one could produce food that would substantially reinforce the immunological system in humans. Imagine we are looking at the possibility of creating armies of white-blood cells capable of living unaffected in a sea of HIV.

Our scientist runs off to the patent office, tells the world what gene is responsible for the production of Vitamin X and shows the world how to enhance it in wheat. A valiant entrepreneur then conjures up a way of massively producing Super-Wheat in industrial proportions, pays our scientist for the use of her patent, and sells his seed to whomever will buy. The wheat growers of the world turn to producing genetically enhanced Vitamin X through the production of Super-Wheat. Beer makers use Super-Wheat to produce beer and the AIDS epidemic is solved in the middle of euphoric feasting and toasting with Super-X Bud.

Second image: our same scientist has toiled for 2 to 10 years screening the genes of mice, microbes, and moose and has found nothing worth writing home about. In desperation she takes a couple of days off and goes to Turkey for scuba-diving lessons on the Aegian Sea. While drinking beer at the beach she reads a newspaper article on a hospital that has several cases reported of HIV-positive patients who in 15 years show no signs of developing AIDS. She rushes off to the remote mountainous city where the hospital is located. She figures out that all patients with HIV who have survived without developing AIDS have an extraordinary immunological system. She tests the HIV-positive patients and finds that they all have high levels of Vitamin X in their blood and that they all come from the same farming community nearby. She rushes to their home village to inquire about their diet, habits, and habitat. She is told that in that Eastern Orthodox community the local priest uses sacred bread when performing the religious ceremonies of the

community, from which all villagers eat every morning. The bread is made from wheat, grown only for religious purposes. The bread is thought to be miraculous and the wheat is grown only from fields at the foot of a nearby volcano.

Our scientist acquires a sample of the wheat, flies back home to New Haven, evading the Turkish customs officers by hiding the sample wheat among her scuba-diving equipment. Upon her arrival, she contrasts the Turkish wheat to more common strands of wheat and pinpoints the genetic mutation that is responsible for the over-production of Vitamin X. She runs to the patent office, gets a patent for her company. The patent is then licensed by a big agro-business company, which in turn produces the wheat and commercializes the beer at $200 per can. After years of protests for cheaper beer and millions of deaths due to AIDS in Africa, the African governments announce that they will disregard the patent and allow aids.org, a non-profit NGO dedicated to medical relief in poor countries, to produce the generic beer at affordable prices. Half of the African continent (the poorer half) is embargoed by the WTO for three years before the issue is solved through an agreement with Super X Bud, Inc. in which the price for the beer is set at $15 per can.

The two stories have several things in common. To begin with, they are both ludicrous. But that aside, they both give a key role in the development of Super X Bud to our Neoheavenite and they both reflect how, in the end, the population suffering from HIV is benefited by the ordeal. However, they differ in that the second story includes a broader picture and shows that the Turks, both as a social and a political community, are excluded from the first story.

The fact is that knowledge does cross over both ways, from traditional communities to biotech industries and from biotech industries to developing countries where some of these traditional communities dwell. Pharmaceutical Companies *do* send researchers off into the Amazonian jungle to inquire about traditional medicines;[3] Western countries *have* granted patents on plants that are used as basic foods and medicines by entire

[3] See, among others, Ana Paula Corazza, *Bio Plunderers* in Brazzil, March 2001 at http://www.brazzil.com/p24mar01.htm and Howard LaFranchi, “Amazon Indians Ask 'Biopirates' to Pay for Rain-Forest Riches” in Christian Science Monitor, Thursday November 20, 1997 at http://csmweb2.emcweb.com/durable/1997/11/20/intl/intl.2.html

nations, such as the *basmanti* rice in India.[4] In Mexico, peasants *have* been banned from exporting the yellow *enola* bean, developed over centuries of traditional selective breeding in north-west of Mexico, to their larges potential market -the United States- because an American entrepreneur was granted a patent over the bean. [5] The pharmaceutical company Eli Lilly has made over a hundred million dollars from medicines[6] developed from *rosy periwinkle*, a plant traditionally used in Madagascar for medicinal purposes and identified by the pharmaceutical partially on the traditional knowledge of communities that used it.[7]

The value of the knowledge thus appropriated, is not negligible:

> The current value of the world market for medicinal plants from leads given by indigenous and local communities is estimated to be $43 billion. Using traditional knowledge increased the efficiency of screening plants for medical properties by more than 400%.[8]

These estimates are only for medicine. If we factor in food, the value of the market is notoriously higher.

The phenomenon is often referred to as biopiracy: "Biopiracy occurs when genetic resources and traditional knowledge is taken from biodiverse developing countries without permission."[9] The metaphor, I posit, is misleading. Piracy draws our attention to the pirate, who takes without permission, without right, without legal entitlement. What is happening with biodiversity under the current international patent law system is not piracy, for the law sanctions it. It more closely resembles colonialism, by which dominant powers "lawfully" appropriate the resources of dominated peoples.[10]

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[4] Vananda, Shiva, "Poverty and Globalisation", BBC Reith lecture delivered in New Delhi, India, see http://www.biotech-info.net/poverty_globalisation.html

[5] "The Right to Good Ideas", The Economist, August 15, 2001 at http://www.biotech-info.net/right_to_ideas.html; see also http://www.grain.org/sp/publications/biodiv235-sp.cfm

[6] *Vinblastine* and *vincristine* are two drugs that respectively are used to treat Hodgkin's disiease and childhood leukemia.

[7] *See infra* 9 at 89.

[8] Vananda, Shiva, "The politics of knowledge at the CBD", THE THIRD WORLD NETWORK, http://www.twnside.org.sg/title/cbd-cn.htm (last visited, April 2011).

[9] John Reid, "Biopiracy: The Struggle for Traditional Knowledge Rights", AMERICAN INDIAN LAW REVIEW, Vol. 34, No. 1 (2009-2010), pp. 77-98

[10] This parallel has also been observed by Vananda Shiva, see *infra* note 16, as well as Rebeca Bratspies, *see* Rebeca M. Bratspies, *The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional*

Colonial powers developed highly sophisticated legal doctrines to justify their actions and to protect their claims from both other colonialists and native peoples living on the appropriated land. Among those doctrines was the idea that land not occupied by a *proper* polity was there for the taking.[11] Of course, most often than not, polities did occupy the lands, but they were invisible to European law, for they did not resemble, to *enough* degree, their own policies. Patent law today resembles colonialism; it is no longer necessary to occupy a foreign land to appropriate its resources or to conquer a people to expropriate their knowledge, one can patent them. As before, however, it is not because there is no knowledge of how to use those resources or no innovation in using them, but rather because the knowledge and innovation of peripheral communities is rendered invisible by the international system of patent law, just as the political communities that inhabited colonized lands were rendered invisible by colonialist legal doctrines.

The Claim

"Upstream" patents are patents needed by other innovators to work on their own innovations; "downstream" patents are patents that rely on upstream innovation to innovate further. Much of the criticism to patent law as applied to genetic research and its commercialization is concerned with "upstream" patenting hindering "downstream"

Knowledge, American Indian Law Review, Vol. 31, No. 2, Symposium: Lands, Liberties, and Legacies: Indigenous Peoples and International Law (2006/2007), pp. 315-340. While Shiva and Bratspies propose to rethink the foundations of Western property regime (Bratspies holds that "[t]he international community needs to rethink the very idea of property -which people should be entitled to claim what sorts of rights over things and under what conditions?"), my critique here is far more modest (which does not mean I don't agree with the two authors): for now, I simply want to point out the inequities of the international intellectual property regime as it intersects with US patent law, that stem from its inconsistencies: it protects "upstream" innovators, but selectively stops short of going fully "upstream" to the source of the knowledge on biodiversity; it recognizes the potential value of traditional knowledge, but tailors rules so as to exclude foreign traditional knowledge from protection against undue appropriation.

[11] First, Europeans posited that indigenous people were not *proper* human beings and that their communities were not *proper* polities. This thesis was questioned and resolved in favor of considering them human beings. For a rich analysis of this debate and its consequences on Western thought, see ANTHONY PAGDEN, THE FALL OF NATURAL MAN: THE AMERICAN INDIAN AND THE ORIGINS OF COMPARATIVE ETHNOLOGY, (Cambridge University Press 1982). Yet even among the "defenders" of indigenous population to whom it was a settled issue that indigenous Americans were proper human beings and that their communities were proper polities, doctrines were proposed that justified colonization: if natives resisted evangelization, Europeans had a duty to use force to protect those disseminating the word of God. See, for instance, FRAY ALONSO DE LA VERA CRUZ, *DE DOMINIO INFIDELIUM ET IUSTO BELLO*, I-II (Roberto Heredia Correa trans.) (UNAM-Instituto de Investigaciones Filológicas 2000). An English translation by Ernest J. Burrus, S.J. of the work of Vera Cruz has been published by the Jesuit Historical Institute, 1968.

development of products by "stacking" patents, that is, by patenting the chain of ideas, making downstream innovation more expensive insofar as it needs to pay for upstream patents.[12] This critique points out that patenting biology –including genetic information– forces those willing and capable of doing research with that information to pay for it. A scientist has to pay different "toll booths" –i.e. patents– to be able to continue her research, making research more expensive and development slower. The basic argument of this critique is that patent law, by protecting "upstream" actors, hinders "downstream" researchers and with them, research and innovation. While this debate is very important[13], I want to reorient the focus of the discussion on patent law of genetic information and material. I want to suggest that we also need to turn our heads *further* upstream, where innovation is not protected or even recognized; and I also want to make the argument that we should be concerned not only with the potential for innovation that patent law enables or obstructs, but also with the resulting distribution of benefits that derive from innovation. Not turning our heads *further* upstream means excluding from the partition of the spoils major contributors to genetic knowledge and application.

There are two resources that the developing world typically brings to the table of the genetics revolution: knowledge and raw materials. It brings knowledge in the form of traditions that can identify species of plants and animals with valuable genetic properties, which are either found in nature or have been developed through centuries of selective breeding. It also provides the raw material from the genetic resources of their lands.[14] The countries that most prominently supply both often coincide: 9 of the 13 megabiodiverse countries are also culturally diverse countries.[15] Cultural diversity coupled with

[12] See Michael A Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research* 280 Science at 698-701, as cited in LORI B. ANDREWS ET. AL. *Supra* at 1 172.
[13] ADD FOOTNOTE EXPLAINING FURTHER UPSTREAM-DOWNSTREAM CRITIQUE.
[14] Most relevant in matters of biological diversity and genetic resources are the countries identified as mega-biodiverse, that is: exceedingly rich in biological diversity. There is no stable list of mega-biodiverse countries, but usually the following are identified: Australia, Brazil, Bolivia, China, Colombia, Ecuador, India, Indonesia, Madagascar, Mexico, Peru, United States, Venezuela, and Zaire. Other countries rich in biodiversity include Costa Rica, Cuba, Fiji, Philippines, Gambia, Malaysia, Nigeria, South Africa, and Thailand. Jorge Caillaux and Manuel Ruiz, *Experiencias legislativas sobre acceso a recursos genéticos y opciones para los paises megadiversos*, document prepared by the Peruvian Society of Environmental Law for the Ministerial Sumit of Megadiverse Nations in Cancun, Mexico held on February 16 through 18, 2002 at 1.
[15] ADD FOOTNOTE

biological diversity are a potential source of wealth, yet both forms of diversity are underprivileged in the current intellectual property rights regime.

My main criticism is that this knowledge is invisible to the legal instruments that adjudicate (intellectual) property rights and benefits. Also, the raw material (the genetic resources contained by biodiversity) is, for all practical purposes, rendered a new *terra nullius*, ready for the taking.[16] The landscape of genetics is empty in the eyes of patent law: it sees not the people who provide vital information for genetic research and it sees not the nations who claim sovereignty over their natural resources. The way patent law plays out in the field of genetics, is as if the Pilgrims had not invited the Indians to Thanksgiving.

This disparate allocation of benefits, it can be argued, is nothing new. True, but none-the-less it is relevant to point out both old and new legal mechanisms that result in disparate distributions of wealth, which reinforce the widening gap between rich and poor. And in the case of genetics, it seems even more relevant to point out the dangers of being selectively enthusiastic in a developing industry that deals with one of the most important things we produce: food.

The Legal Framework

The intersection between intellectual property rights and genetics takes place on two levels: the national and the international. The following paragraphs seek to broadly locate the legal framework through which national patent laws and international trade agreements fit together to provide for the patenting and commercialization of genetic information. In the last section I will contemplate some arguments as to how this

[16] The analogy with the *Terra Nullius* is not mine, but Vananda Shiva's. I borrow it because it is certainly powerful and illustrative as to how the legal concepts of a society can render entire societies or their claims invisible: "The epidemic of biopiracy is rooted in the old colonial assumption of '*Terra Nullius*' or empty earth –if a territory is empty of "white Christians" it is assumed to be empty. Today, the 'empty earth' has been replaced by empty life –plants, animals, micro-organisms and humans become 'inventions' when their knowledge is discovered by Western science or Western commercial interests, even if this knowledge has existed for centuries in indigenous cultures, and even though life forms are not human inventions. Patents on life are based on biopiracy, either because they involve the theft of nature's creativity and intelligence or the creativity and innovation of other cultures." Vananda Shiva, *North-South Conflicts in Intellectual Property Rights*, Peace Review 12:4 (2000), 501-508.

framework fails to provide for a suitable scheme of benefit sharing between the different agents involved in exploiting the genetic resources of the world.

On the international arena the most relevant legal instrument is the agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization.[17] It was developed for insuring strong intellectual property rights for all of its members. The TRIPS agreement was hammered out at the Uruguay Round of trade negotiations and came into effect on January 1st, 1995. Its most relevant effect was to have all member states recognize intellectual property rights issued by other member states. Because of this, a patent registered in one member country must be respected by other member countries. This allows players, such as the biotech industry, to bypass local patent law by registering their patents in the most favorable jurisdiction.[18]

> Traditionally, intellectual property was a domestic, rather than an international issue; states were free to set their own level of protection based on their particular circumstances. TRIPS changed all that by establishing universal and uniform standards for property intellectual law.[19]

[17] Another international treaty, the Convention on Biological Diversity (CBD), which came into force on the 29th of December of 1993, is often invoked as a counter weight to the TRIPS agreement. Article 8(j) speaks to the issue of traditional knowledge and the distribution of benefits that come from it (it states that the parties shall "to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." CONVENTION ON BIOLOGICAL DIVERSITY, United Nations, 1992. Although very important, I do not engage in analyzing this Convention and the dispute over what issues fall under which convention for two reasons. First, because the thrust of the convention has to do with the conservation of biodiversity, not so much its exploitation. Second, and more importantly for practical reasons, because the United States has signed, but not become a Party to the Convention, thus making TRIPS the international instrument regulating the exploitation of biodiversity in the single most important jurisdiction where such exploitation plays out. Even if the US was a Party to the Convention, its enforcement mechanisms pale in comparison to the WTO's, *see* Bratspies, *supra* note **Error! Bookmark not defined.** at 330.

[18] *See* Gian Carlo Delgado, *Biopiracy and Intellectual Property as the Basis for Biotechnological Development: The Case of Mexico*, International Journal of Politics, Culture and Society, Vol. 16, No. 2, Winter 2002.

[19] Bratspies, *supra* note **Error! Bookmark not defined.** at 323. Bratspies explains how this uniform regime came about: "Indeed, TRIPS was intended to standardize these differences in intellectual property protection between the nations of the global north and the global south. Because the United States, the European Union, and, to a lesser extent, Japan wield tremendous influence in the WTO, their voices drew the most attention in the process of drafting the TRIPS agreement. These nations were, in turn, influenced

Because of this arrangement, the most relevant intellectual property rights for *all* countries are those granted in the developed world and specifically by the United States. At the close of the 20th century, the United States alone was responsible for 41.8% of the patents filed in the world while all of Europe put together amounted to 41.95%[20]. Given these numbers one can safely state that relevant patenting regulation is to take place in these nations, so analysis of the intellectual property regimes of the developing world, while important, remains secondary.

TRIPS

In order to understand the orientation that the legal framework takes, and, later on, account for the failure to recognize the value of traditional knowledge in the production process, it is important to first point out the explicit objectives which are set forth by the TRIPS: they revolve around the idea of *technological* development, with broad benefits for all involved, as stated in **Article 7:**[21]

> The protection and enforcement of intellectual property rights should contribute to the promotion of **technological innovation** and to the **transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to **social and economic welfare**, and to a balance of rights and obligations.

As is clearly stated, the central concern of the agreement is with technology and technological innovation. Article 7 establishes as central objectives a) the promotion of technological innovation; b) the transfer and dissemination of technology; and c) the mutual advantage of producers and users of technological knowledge. If one thinks not in

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by the commercial interests of their corporate citizens. In fact, the TRIPS agreement was drafted and introduced in the Uruguay Round of GATT by an American industry coalition, the Intellectual Property Committee (IPC), which conducted what it called 'missionary work' to sell the idea to the international community."

[20] Table 1: Patent applications to the Patent Cooperation Treaty, 1997, from Dutfield, G. *Intellectual Property Rights, Trade and Biodiversity: The Case of Seeds and Plant Varieties.* IUCN, Gland and Earthscan, London; as cited by Juma, C. (1999). *Intellectual Property Rights and Globalization: Implications for Developing Countries.* Science, Technology and Innovation Discussion Paper No. 4, Center for International Development, Harvard University, Cambringe, MA, USA.

[21] World Trade Organization *Agreement on Trade-Related Aspects of Intellectual Property Rights* at www.wto.org (TRIPS). Highlights are mine.

terms of abstract objectives, but in terms of the people involved, and concretely with regards to the area of genetic biotechnology, we can see that the objectives set forth by TRIPS put the following specific actors in the forefront: a) producers of technological innovation and b) users of technological innovation developed elsewhere. That is, basically, researchers and developers, both publicly and privately funded. Of course, "social and economic welfare" is mentioned, but the relevance of this part of the text is negligible because a) "everybody" is as good as "nobody" and b) in making "social" and "economic" aspects of one "welfare" the two terms become undistinguishable and thus of little use.

Most eloquent in this article are its omissions. Nowhere do we see the actors that are often found the furthest upstream in the production of biotechnological products: the communities that produce the traditional knowledge used in the identification of valuable genetic material. Formally, the owner of the genetic resources used in the production of biotechnological products is usually the State,[22] and, in the case of genetics, it's usually a megabiodiverse state. Patent owners, however, are the ones capable of *exploiting* these genetic resources by patenting the genes or organisms in a jurisdiction protected under TRIPS, without compensating the state that nominally owns those resources. What good is property if exploitation is someone else's entitlement?

Moving from objectives to regulation, Article 27 establishes what a "*Patentable Subject Matter*" is:

> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether **products or processes**, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. … [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and **whether products are imported or locally produced**.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *public*

[22] Jorge Caillaux, et. al. See *supra* 6 at 8. Of the 13 states mentioned in the document, 10 establish that the rights over genetic resources belong to the state. Also, the Convention on Biodiversity establishes state-ownership of genetic resources.

> *order* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and **essentially biological processes** for the production of plants or animals **other than non-biological and microbiological processes**. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.[23] The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 27 allows for the patenting of new "products or processes" "capable of industrial application". The novelty aspect presumably requires only that the product or process "involve an inventive step".

> Typically, a gene patent claims to cover a purified and isolated gene, the protein for which the gene codes, cells or biological entities that have been engineered to express the gene, the process by which the gene was purified, and the use of the gene or protein to detect or treat a disease or condition.[24]

When speaking about genetics, "products" seems to refer to a) an isolated gene, b) the protein coded by a gene or c) microorganisms (such as bacteria) engineered to express the gene; "processes" refers to a) the process by which the gene was purified, or b) the use of the gene or protein.

The novelty and the "inventive step" refers to, in our subject matter, to the manipulation of genes through sophisticated technology. The text differentiates "essentially biological" processes, which are excluded from the agreement's protection as innovative procedures, from "microbiological" and "essentially non-biological", which warrant protection through patent law. This means that genetic manipulation Mendel-style (selective

[23] COMMENT ON ARTICLE http://ecologic.eu/download/projekte/1800-1849/1802/wp7_final_report.pdf
[24] LORI B. ANDREWS ET. AL. See *supra* 1 at 146

breeding) is not considered innovative, for it is “essentially biological”. The products of selective-breeding-based genetic manipulation, that is, the organisms that manifest the genetic enhancement, aren’t protected by TRIPS either. The genetic manipulation considered innovative and valuable, and hence worthy of legal protection through intellectual property rights, is that which involves sophisticated techniques of laboratory manipulation of a cell nucleus.

These distinctions, of course, are not analytically necessary. Why is it that a protein or a cell used to express the gene in high-tech procedures is protected under TRIPS, but a plant used in selective breeding procedures to express that same gene is not? The difference in size of the living matter manipulated is a difference of degree, not kind. The same can be said for the biological/non-biological dichotomy. How non-biological does a procedure need to be? What does “essentially biological” mean? Is it different from non-essentially “biological”?

In short: under TRIPS, producing genetically enhanced organisms through selective breeding does not qualify as a valuable intellectual endeavor worthy of legal entitlement to a temporal monopoly on either the product of the genetic manipulation or the process of manipulation. On the other hand, producing genetically enhanced organisms through methods other than selective breeding that involve intensive human and technological capital (a sophisticated laboratory, staffed) entitles the owner of such means to a temporal monopoly on both the product and the process.

The highly abstract terms of Article 27 translate into the very concrete distinction: high-tech processes and “micro” biological products (which usually require high tech resources to isolate and sustain) are protected under TRIPS, whereas low-tech processes and “essentially biological” (i.e. “natural”) products are excluded. It takes no genius to correlate patent protection with types of actors involved in the development of biological resources.

Domestic law: the relevant case of the United States

The TRIPS agreement leaves plenty to discretion. What is to be considered “products”, “innovative”, “novel”, and “non-biological”, are difficult matters to determine, and in the

case of genetic biotechnology crucial and debatable issues. In order to understand how intellectual property rights are tied to biopiracy we need to look at the municipal law of the nations that harbor biopirates.[25] I will take up the United States as an example that is not only illustrative but also important to the overall workings of the international patent system in itself.

U.S. law requires these inventions to be "novel", "nonobvious" and "useful".[26] Intuitively we think of patents as excluding that which is naturally occurring; that which we "find" and not "create". In the United States this is not so. The power to grant patents is a broad entitlement that the Constitution grants to Congress.[27] Congress has regulated this matter through 35 U.S.C., specifically §§ 101-103. The law basically requires 4 conditions for granting a patent: a) novelty, b) non-obviousness of the invention, c) usefulness, and d) that the petitioner of a patent include in the application a description which is "enabling", that is: which allows someone sufficiently skilled to reproduce the invention.[28] The U.S. Patent and Trademark Office has determined that a genetic sequence[29] is patentable if it and its function are described. It has also deemed sexually reproducing plants patentable.[30] The Supreme Court has not pronounced itself on the matter, although arguably there are applicable precedents that point to the impossibility of patenting

[25] I use the term "biopirates" because it is already so widely used, but a more adequate term, in my opinion, would be "patent colonialists".

[26] For the United States see 35 U.S.C. §§ 101-103; for Europe see Article 3 paragraph 1 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, http://europa.eu.int/eur_en/lif/dat/1998/en_398L0044.htlm. On the international sphere, the TRIPS agreement specifies, in a footnote to Article 27 paragraph 1 that "[f]or the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively." See TRIPS, supra note 21.

[27] CONST. Art. 1 § 8, cl. 8

[28] LORI B. ANDREWS ET AL. *Supra* at 1. 145-147

[29] Not only full genes can be patented, but also gene fragments; single nucleotide polymorphisms or SNPs, which are alterations of one nucleotide (what Riddley calls letters, see bellow 36) in a gene sequence; gene tests, and proteins produced by specific genes. See U.S. Department of Energy Office of Science, Office of Biological and Environmental Research, Human Genome Program. http://www.ornl.gov/hgmis/elsi/patents.htlm, "Genetics and Patenting" in LORI B. ANDREWS, ET AL. See s*upra* 1 at 161-165.

[30] *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interferences 1985).

"natural phenomena, that is, principles, powers, and products of nature".[31] Lower courts have upheld patents on "purified" natural substances, such as vitamins.[32]

Importantly, the novelty requirement is different for traditional knowledge originated in the United States than knowledge originated abroad. Traditional knowledge originating within the United States –say, traditional medicine of Native American tribes– cannot be easily patented. If someone tried to patent it, and it can be proven to have been around in oral or printed form, it will not be considered novel. This is not so, however in the case of traditional knowledge generated abroad: it needs to be published in order not to be considered novel.[33] If foreign traditional has only been registered through oral tradition, it can be patented as novel in the United States.

> Traditional knowledge that is handed down for generations outside the United States can be used and patented within the United States. As long as there is no public written record, a United States company can go into a foreign country and use knowledge handed down by indigenous peoples to obtain a patent. The company *would be engaging in biopiracy, but would be breaking no law*. Another problem is that once the company has published the traditional knowledge, it prevents indigenous peoples from patenting or profiting from the knowledge in the future. A researcher can also gather knowledge from indigenous peoples and publish it in an academic publication, preventing indigenous peoples from later patenting the knowledge.[34]

Whether a gene qualifies as a purified natural substance or as a product of nature whose function is a natural occurring phenomenon, can be the matter of interesting debates. But until the issue is either solved differently at the lower courts or brought before the Supreme Court, the Patent Office has the decisive opinion. The fact is that, under the rationale that considers described genes as purified natural substances, researchers and biotech companies can patent genes and genetic sequences if they describe the genes and figure out their function. The gene thus becomes a "product" protected by TRIPS and the

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[31] Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-dissipating Races* 43 UCLA L. Rev. 961, 964-968, 985-992 (1996) in LORI B. ANDREWS ET AL. See s*upra* 1 at 149-152
[32] *Merck & Co. v. Olin Mathieson Chemical Corp.* 253 F.2d 156 (4th Cir.1958)
[33] 35 U.S.C. §102(a). European patent law, in contrast, does not distinguish in this respect between knowledge generated abroad and knowledge generated within its borders.
[34] *See* Reid, *supra* note 9 at 82. Emphasis added.

applications derived of knowing the information coded in a gene, or genetic sequence, are "procedures", also protected by the agreement. Because the "isolation" of the gene is considered a non-biological procedure and its manipulation micro-biological, the patents over them are not excluded from the agreement.

What does this mean?

> When a company is issued a gene patent, it gains exclusive rights to commercialize the patented gene. Most companies' primary method of commercially exploiting patented genes is through agreements in which they license others to use their patents. […] A company is also free to prevent others from using its patented gene. The company can then develop commercial products utilizing its patented gene and enjoy the monopoly on those products that a gene patent provides.[35]

In a very real sense, a patent holder to a gene appropriates the gene. She also appropriates the uses of that gene. Of course, because of the requisite that foreign traditional knowledge be published, foreign communities which generate traditional knowledge find themselves in a catch-22 situation: if their traditional knowledge, handed down orally, has been published, it is not novel; if it has not been published, it is vulnerable to patents by Americans, but not themselves.

Translating facts into legal jargon

Social justice considerations aside, let us concentrate on the analytic categories and conceptual consequences of the legal framework for patenting genetic innovations. There are two sets of problems. One relates to the notion of "innovation", the other to the arbitrariness of the distinctions between the procedures that are susceptible for patent and those that are not.

Patents are supposed to reward innovation. How can a gene (unaltered), which is found in nature, be considered an innovation? Genes and genetic sequences are basically information.[36] They are codes for producing proteins. Where is the innovation in looking

[35] LORI ANDREWS ET. AL. See s*upra* 1 at 146.
[36] For example, Matt Ridley in his bestselling book on the human genome uses a literary metaphor. "Imagine that the genome is a book.

hard into nature and figuring it out? What is the difference between finding a gene and coming up with a use for it, and finding another product of nature, say an ox, and finding a use for *that*? Why aren't oxen patentable if they are useful for tilling the land? Genes (unaltered) and genetic sequences (unaltered) can be either products of nature or pieces of information available to be read. In either case, where is the innovation?

For innovation we need to turn to the procedure for describing the genes. But here again there are two options: a) the procedure used is a standard procedure which is learned and so only seldom does a procedure come along which is truly an innovation (i.e. a new procedure was developed which substituted selective breeding for one that involves nucleic manipulation); or b) a different procedure is developed every time a gene is described. In the case of a) we should grant patents to those people who come up with truly innovative procedures (more power to you!). In the case of b) the definition of innovative procedure would have to mean something like "recipe" and would need to be so broad as to include procedures for coming up with new subspecies of dogs (for example: "the procedure for obtaining a *Monster* dog is by breeding a *Chihuahua* dog with a 50% *Mastiff* dog and 50% *Shar-pei* dog"), race horses, or bulls; but arguably they all use a very "natural" procedure, i.e. sexual reproduction, which I doubt someone could call "innovative".

Second problem: the categories and subdivisions recognized in the legal instruments are clearly arbitrary. They are tailored to exclude certain types of knowledge (*basmanti* rice is good for children) and include others (*basmanti* rice contains a mutation of gene X which enhances the production of calcium and hence the development of young children who eat it). It is also tailored to exclude certain methods ("breed a Chihuahua with a half-Mastiff, half-Shar-pei" or "every two years exchange half of your seeds with your neighbor down the valley to get bigger corns") and recognize others ("get a big lab and

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There are twenty-three chapters, called CHROMOSOMES.
Each chapter contains several thousand stories, called GENES.
Each story is made up of paragraphs, called EXONS, which are interrupted by advertisements called INTRONS.
Each paragraph is made up of words, called CONDONS.
Each word is written in letters called BASES." See MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS at 7 (1999). Other popular metaphors are culinary ("recipes") and cybernetic ("code").

many Ph.D. students so that you can inject the chromosome of a live Chihuahua into the egg of a half-Shar-pei-half-Mastiff ").[37]

There are no solid analytic distinctions between the "products" and "processes" which are protected by intellectual property rights and others that are not. The only plausible explanation is to say "we highly value biotechnology and sophisticated genetic information and we don't care much for selective breeding and traditional knowledge". But here lies the paradox: biotechnology and genetic research highly value both the products of selective breeding and the information on genetic characteristics which are not coded in scientific language, but in the language of tradition.

The paradox

There are approximately 32,000 genes in the human genome.[38] There are an estimated 40 to 50 million species on the planet of which only 1.7 have been documented.[39] Not all species have as many genes as humans, but this gives us an idea of the universe of genetic information that is out there. There are lots of genes. Researchers need and use all the help they can get. They often turn to traditional knowledge. The use of known vegetable genetic resources and the traditional knowledge they are tied to can reduce between 2 to 10 years the time needed to develop a new pharmaceutical products, representing up to 50% reduction in research costs of pharmaceutical and cosmetic industries.[40] The problem is that this reduction in costs and the corresponding rise in profits are not shared by the communities that provide the knowledge or the nations that provide the genetic resources that translate into those profits.

[37] The logic behind these dichotomies summons up the ghost of the *Lochner Era* jurisprudence: in-the-flow-of-commerce/out-of-the-flow-of-commerce, direct/indirect, and other such dichotomies. Creating analytic categories into which one can classify phenomenon and distinguish one phenomenon from the other is not difficult. What is difficult is for such a classificatory activity to be unbiased.
[38] LORI B ANDREWS ET. AL. *Supra* at 1 6
[39] Juma, C. See *supra* 8 at 15
[40] *Genetic Resources and Intelectual Property Rights*, Presentation by Brazil for the Ministerial Summit of Megabiodiverse Nations in Cancun, Mexico held on February 16 through 18, 2002.

There are simultaneous but opposing moves at play in the legal regulation of gene patents. On the one hand, excitement about genetics takes over and the law makes description equivalent to "invention". Describing a gene is regarded as such a powerful act that it warrants appropriation of the gene. The analogy to creation and the god-like narrative of genetics makes itself present. So when considered for its intellectual value, sophisticated, technologically-intensive genetic research is exalted and showered with prizes and properties, while less capital intensive genetic materials and knowledge are disregarded as invaluable.

On the other hand when considering the types of legal instruments that will regulate those rights, genetics is nothing special, it just fits in with other "innovations" and falls within patent law. It has been argued that patent law is not the appropriate regime for genetic development because patents are designed to grant rights in exchange for information, whereas in genes all that there is, is information, and thus the information itself is appropriated with no corresponding benefit to society; because there are few safeties built into the regulation for competing interests of the public; and because much of the development is due to public investment in research and not so much creativeness of the part of the researchers.[41] On my part, I add the argument that it is not the appropriate regime because patent law renders invisible crucial resources, both human and genetic, which go into the development of genetic research but which currently do not profit from genetic research. Here geno-hype would be justifiable: genetic research is special and thus requires a separate legal framework in order to distribute outputs in correspondence with inputs.

This selective hype about genetics is full of sound but is, in many ways, hollow. Rather than hype, we need to take a conscientious look at the peculiarities of the genetic research, development and commercialization so as to provide the legal framework that will reflect reality and better distribute the economic benefits.

[41] Rebeca S Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, in LORI B ANDREWS ET. AL. See s*upra* 1 at 169-172

Conclusions

Today's international intellectual property rights regime has two key components: the TRIPS agreements and US patent law. When applied to genetic wealth and biotechnology, the legal regime systematically excludes from economic benefit two of the key players located further upstream –megabiodiverse countries and indigenous or traditional communities– from where all other participants in the innovation process feed. This exclusion should worry us on two different grounds. First, is justice; second, sustainability.

Colonialism was for the most recent half millennia the dominant international system, legitimized by law and legal doctrine. At its most basic, it consisted of the appropriation, by dominant markets, of the resources and efforts of dominated peoples. With today's current intellectual property regime, we are setting in place the pieces that will render us capable of reproducing the basic structure of colonialism: resources and work (knowledge) of the have-nots are appropriated by the haves, blessed and protected by law. Furthermore, the legal regime being put in place today resembles the old colonial regime: it allows appropriation by being culturally selective. Knowledge and technology used by developing nations and indigenous cultures are invisible to the intellectual property law that allows for the allocation of value to natural and human resources. Thus, although the knowledge traditional societies provide international biotech industries is clearly valuable to the latter, the legal regime does not value the former. This is bad in itself, for it is unjust not to acknowledge the contribution of traditional knowledge and developing, biologically rich countries to the development of food, medicine and other resources from which we all benefit.

But putting justice aside, that the current legal regime on intellectual property rights as applied to genetics and biodiversity will contribute to impoverish both the biological and cultural diversity upon which biotech innovation increasingly relies. I offer these two reasons as tentative hypotheses, which warrant further research. I believe it is important to keep them in mind for they speak to the broader problematic involved in our topic.

First, in denying traditional communities the benefit of profiting from their traditional knowledge, the international intellectual property rights regime keeps them from

obtaining sustenance from traditional activities and push them to seek sustenance elsewhere. In not allowing indigenous peoples and traditional communities to profit from the benefits the biotech industry obtains form their knowledge, they continue to toil in a global economic environment increasingly hostile to them (often made more hostile by the same biotech industry they benefit). The pressure exerted on them is likely to push them into exploiting the resources they have in hand: sale of land or deforestation for sustenance agriculture.

Megabiodiverse regions are also often poor regions, with subsistence-oriented agriculture –that is biodiversity often intersects with cultural diversity and poverty. Subsistence agriculture helps speed up deforestation:

> In permanent cultivation, the expansion of **food-crop cultivation for subsistence is three times more frequently reported** [as a cause for deforestation] than the expansion of commercial farming (less than 25% for all regions). In shifting cultivation, cases of deforestation driven by slash-and-burn agriculture are more widespread in upland and foothill zones of Asia than elsewhere, whereas when practiced by colonizing migrant settlers in Latin America, it is mainly limited to lowland areas. Pasture creation for cattle ranching is a striking cause of deforestation reported almost exclusively for humid lowland cases from mainland South America.[42]

The second reason is related: if traditional peoples cannot participate in the world economy as collective conveyers and/or developers of knowledge, then they are left to participate as individual workers. Under enough pressure, they will adapt and adopt different traditions or migrate to different environments where they can access different, better acknowledged (though less valuable) economic opportunities. In doing so, they tend to disappear *as communities*, and their untapped knowledge with them. It would be smart –not to mention fair– to integrate the peoples who both inhabit and *know* the natural resources that are the source of our "stream" of innovation into the economic

[42] Helmut J. Geist and Eric F. Lambin, *Proximate causes and underlying driving forces of tropical deforestation*, BIOSCIENCE, February 2002, ProQuest Biology Journals. Emphasis added.

benefits of innovation, lest they not value what they stand on and contribute to their destruction or else disappear altogether, with their knowledge.

As colonialism is condemned today by the emerging International Human Rights Law system, a new form of neocolonialism is being set in place again by the Intellectual Property Rights Law system. Granted, it is not as brutal or visible as its predecessor (at least not yet), but its logic is similar and its core conceptual underpinning –rendering the other invisible to the law– identical. It is also potentially as dangerous: it continues and deepens the logic of appropriation for exploitation of both natural resources and peoples. Justice and pragmatics intersect: we have to both *do justice* to traditional communities and developing nations *and* structure the legal regime to insure *long term sustainability* of biological and cultural diversity. Unless we value both resources –biology, biodiversity and biological systems– and peoples in and of themselves, the logic of exploitation will likely drive us to their destruction. We seem not to have learned from history that the exploitation of both peoples and lands is unsustainable in the long run.